IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CHEMISTRY COUNCIL, INC.,	:	
Plaintiff,	:	Civil Action No. _____
v.	:	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, and NATIONAL CANCER INSTITUTE,	:	
Defendants.	:	

COMPLAINT

Plaintiff American Chemistry Council, Inc. (the "Plaintiff"), by and through its undersigned attorneys, for its Complaint, alleges as follows:

INTRODUCTION

1. By this action, Plaintiff seeks relief directing the United States Department of Health and Human Services ("HHS"), the National Institutes of Health ("NIH"), the National Institute of Environmental Health Sciences ("NIEHS") and the National Cancer Institute ("NCI") (each, a "Defendant"; collectively, the "Defendants") to produce information withheld in violation of the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*

JURISDICTION AND VENUE

2. This action arises under the laws of the United States. Accordingly, the jurisdiction of this Court rests on 5 U.S.C. §§ 552(a)(4)(B), 702; 28 U.S.C. § 1331; and 28 U.S.C. § 1361.

3. Venue is proper in this District pursuant to 5 U.S.C. §§ 552(a)(4)(B), 703; and 28 U.S.C. §§ 1391(b), (e)(1).

THE PARTIES

4. Plaintiff is a nonprofit trade association organized under the laws of the State of New York and having its principal place of business at 700 Second Street, N.E., Washington, DC 20002. Plaintiff represents the leading companies engaged in the business of chemistry.

5. Defendants are agencies of the United States within the meaning of 5 U.S.C. §§ 552(f) and 701(b). Defendants also are awarding agencies within the meaning of OMB Circular A-110 (as codified at 2 C.F.R. § 215.36) and 45 C.F.R. § 74.36. Defendant NIH is a component entity of HHS. Defendants NIEHS and NCI, in turn, are component entities of NIH.

FACTUAL HISTORY

I. The Report on Carcinogens

6. In 1978, Congress mandated that the Secretary of HHS (the "Secretary") "publish a biennial report which contains . . . [, *inter alia*,] a list of all substances . . . [that] are known to be carcinogens or may reasonably be anticipated to be carcinogens and . . . to which a significant number of persons residing in the United States are exposed [and] . . . information concerning the nature of such exposure . . . ." 42 U.S.C. § 241(b)(4)(A)-(B).

7. The Secretary delegated responsibility for the preparation of this report to the National Toxicology Program ("NTP"), a component entity of HHS, which regularly releases the

Report on Carcinogens (the "RoC"). Twelve RoCs have been published since the report was first mandated.

8. The RoC is intended to be utilized by, *inter alia*, state, federal and local regulatory authorities as a "comprehensive" report of "all known or suspected carcinogenic agents." H.R. Rep. No. 95-1192, at 28 (1978). Consistent with this objective, several agencies have promulgated regulations that impose obligations with respect to "carcinogens", where that term is defined, in part, by reference to the RoC. *See, e.g.*, 29 C.F.R. § 1910.1200(d)(4)(i), (g)(2) (the Occupational Safety and Health Administration obliges employers to obtain or develop material safety data sheets with respect to carcinogens that the employers manufacture, import or use); 40 C.F.R. § 707.60(c)(2)(i) (the Environmental Protection Agency ("EPA") requires exporters to provide notices of export for chemicals containing a certain percentage of carcinogens).

II. Formaldehyde and the Report on Carcinogens

9. Formaldehyde is a colorless, flammable gas that is used in aqueous solution to manufacture building materials and many household products. The majority of formaldehyde produced in the United States is used for the manufacture of resins, such as urea-formaldehyde, which are used to make adhesives for pressed wood products such as furniture, paneling and cabinets. Formaldehyde in aqueous solution also is used as a preservative in medical laboratories, mortuaries and consumer products. Further, formaldehyde gas is a byproduct of automobile combustion. Formaldehyde, which is essential for metabolic processes, is produced and exhaled as a gas in small amounts by most living organisms, including humans.

10. Formaldehyde was first listed in the second edition of the RoC, in 1981, as "reasonably anticipated to be a human carcinogen".

11. Until 2011, the RoC primarily limited formaldehyde's potential cancer associations in humans to certain nasopharyngeal cancers and cancers of the nasal cavity or paranasal sinuses.

III. The Zhang Study and Its Use By the Federal Government

12. In 2010, the Journal of Cancer, Epidemiology, Biomarkers & Prevention published a research article reporting on a study on formaldehyde, entitled *Occupational Exposure to Formaldehyde, Hematotoxicity, and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells*. That study is known as the "Zhang Study" because Dr. Luoping Zhang of the University of California at Berkeley School of Public Health was the lead author. Thirty-three other persons co-authored this research article, including eleven individuals who are affiliated with NCI.

13. According to the authors of this research article, the Zhang Study evaluated potential health effects of exposure to formaldehyde, including carcinogenicity, by examining a group of ninety-four workers in China. The authors concluded that formaldehyde exposure can have an adverse effect on the hematopoietic system, and that induction of leukemia (a type of cancer) by formaldehyde is "biologically plausible".

14. Upon information and belief, grants awarded after April 2000 from the Intramural Research Program of the NIH (NCI) and from the NIEHS funded the Zhang Study (grants R01ES017452 and P42ES004705, respectively) (the "Grants"; the recipient thereof being known as the "Grantee").

15. Upon information and belief, the terms of the Grants and applicable regulatory provisions require the Grantee to provide to the Defendants, upon the Defendants' request,

research data relating to federally-funded published research findings that are used in developing agency actions having the force and effect of law.

16. Upon information and belief, in October 2009, a group of scientists participated in a meeting of the International Agency for Research on Cancer ("IARC"), an international agency constituting part of the World Health Organization ("WHO"), that also maintains a list of carcinogens. Based in part on the Zhang Study, these scientists concluded that there was sufficient evidence of an association between formaldehyde exposure and leukemia.

17. In 2010, EPA used the Zhang Study in support of EPA's draft *Toxicological Review of Formaldehyde – Inhalation Assessment* for inclusion in EPA's Integrated Risk Information System.

18. In 2011, HHS published the 12th Edition of the Report on Carcinogens (the "12th RoC") in which NTP classified formaldehyde as "known to be a human carcinogen". NTP used and cited the Zhang Study to support a finding of an association between formaldehyde exposure and leukemia.

19. HHS's publication of the 12th RoC — classifying formaldehyde based upon an association with leukemia using the Zhang Study — has had the force and effect of law, including corresponding regulatory obligations. A federal law requires HHS to issue the RoC for use, *inter alia*, by federal regulatory authorities. For example, as a result of the inclusion of formaldehyde in the 12th RoC as a known human carcinogen, the Occupational Safety and Health Administration requires manufacturers of formaldehyde to obtain or develop material safety data sheets containing information with respect to formaldehyde's classification as a carcinogen.

IV. The Shelby Amendment

20. Congress in 1998 enacted legislation, commonly referred to as the "Shelby Amendment", to ensure public access to data that are developed through federally-funded research carried out by, *inter alia*, institutions of higher education.

21. Specifically, the Shelby Amendment establishes a right of the public to obtain such data by requiring the Director of the Office of Management and Budget ("OMB") to "amend[] Section __.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Pub. L. No. 105-277, 112 Stat. 2681-495 (Oct. 21, 1998). The Shelby Amendment also authorizes the imposition of a reasonable user fee in certain circumstances, to cover the cost of obtaining the relevant data. *Id.*

22. OMB Circular A-110 is entitled "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." The stated purpose of OMB Circular A-110 is to "set[] forth standards for obtaining consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations." In accordance with the directive of the Shelby Amendment, the OMB Director in 1999 amended Section __.36 ("Intangible property") of OMB Circular A-110 to provide as follows:

> [I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency

> obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data.

Final Revision to OMB Circular A-110, 64 Fed. Reg. 54,926-01 (Oct. 8, 1999). OMB later codified this portion of OMB Circular A-110 at 2 C.F.R. § 215.36(d).

23. Other federal agencies have promulgated regulations to codify this portion of OMB Circular A-110. *See, e.g.*, HHS regulations at 45 C.F.R. § 74.36(d). These regulations require compliance by grant-awarding agencies with the procedures established under the FOIA.

V. Plaintiff's Request and Defendants' Response

24. By letter dated November 7, 2011, Plaintiff submitted a request to NIH for "copies of all Records related to" the Zhang Study (the "Requested Records"), including those records associated with the grants that provided funding for the Study. (A copy of the November 7, 2011 request, with enclosures omitted, is attached hereto as Exhibit 1.) Plaintiff's request specified that the Requested Records "may be a part of, or otherwise associated with [the Grants] under the Intramural Research Program of the NIH (National Cancer Institute) and the National Institute of Environmental Health Sciences." *See* Ex. 1 at 1. Specifically, Plaintiff requested three categories of documents,[1] as follows: (i) Records related to the Zhang Study's protocol and methodology; (ii) Records related to information and data obtained regarding the subjects of the Study; and (iii) Records related to analyses, results, findings and conclusions of the Study. *See id.* at 1-2.

25. NIH acknowledged receipt of Plaintiff's request by letter dated November 17, 2011. (A copy of the November 17, 2011 letter is attached hereto as Exhibit 2.)

[1] Plaintiff excluded from the November 7, 2011 request a discrete set of records that Defendant NCI had provided in 2010 in response to a narrower FOIA request related to the Zhang Study.

26. NIH sent a "final response" to Plaintiff's request by letter dated December 1, 2011, signed by Freedom of Information Coordinator Kim Minneman. (A copy of the December 1, 2011 response, with enclosures omitted, is attached hereto as Exhibit 3.) NIH attached to its letter 108 pages of material deemed by NIH to be "responsive" to Plaintiff's request, consisting of the Application for Federal Assistance for Grant #R01ES017452-01 submitted by Dr. Zhang in 2008.

27. Upon information and belief, despite explicit references to NCI in both the Zhang Study and Plaintiff's November 7, 2011 request — and the fact that numerous NCI scientists co-authored the research article regarding the Zhang Study — NIH referred Plaintiff's request only to Defendant NIEHS for response. Accordingly, Defendants did not search the records of any NIH entity other than NIEHS for information responsive to the request.

28. Upon information and belief, NIH also did not request records from the Grantee, as required by the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d). Rather, NIH asserted that such requirements apply only to data which are: (i) first produced under a new or competing continuing grant awarded after April 17, 2000; and (ii) cited publicly and officially by the federal government in support of an agency action that has the force and effect of law. *See* Ex. 3 at 3. NIH contended that the data requested by Plaintiff did "not meet one or both of the . . . criteria"; accordingly, NIH stated that it had declined to forward the request to the Grantee. *Id.*

29. The Grants were awarded well after April 17, 2000. And because the Zhang Study has been "cited publicly and officially by the Federal Government in support of . . . agency action[s]", NIH must be asserting that those agency actions do not "have the force and effect of law".

30. By letter to HHS dated January 4, 2012, Plaintiff timely appealed NIH's December 1, 2011 response. (A copy of the January 4, 2012 letter, with enclosures omitted, is attached hereto as Exhibit 4.) Plaintiff requested that NIH: (i) search the records of NCI and any other NIH entity that may have responsive materials; (ii) provide all responsive materials; and (iii) request responsive materials from the Grantee in accordance with OMB Circular A-110. *See* Ex. 4 at 7.

31. Despite the requirement that the appeal be resolved within thirty days pursuant to 45 C.F.R. § 5.35(b)(2) and (c), to date, HHS has not responded to Plaintiff's appeal.

32. Upon information and belief, Defendants are in possession or control of, or have an obligation to obtain, Requested Records.

33. Upon information and belief, the Grantee is in possession or control of Requested Records.

34. Upon information and belief, the Requested Records were used by the Federal Government in developing agency actions that have the force and effect of law.

CLAIMS FOR RELIEF

COUNT I: VIOLATION OF THE FOIA, THE SHELBY AMENDMENT, OMB CIRCULAR A-110, AND HHS IMPLEMENTING REGULATIONS (5 U.S.C. § 552; 112 STAT. 2681-495; 2 C.F.R. § 215.36(d); 45 C.F.R. § 74.36(d))

35. The foregoing paragraphs are incorporated herein by reference.

36. On or about November 7, 2011, Plaintiff submitted to NIH a letter requesting the Requested Records, pursuant to and in compliance with the FOIA and applicable HHS regulations.

37. Upon information and belief, Defendants are in possession or control of, or have a right and obligation to obtain, all Requested Records.

38. Upon information and belief, the Grantee is in possession or control of Requested Records.

39. In response to a request submitted in conformance with the procedures established under the FOIA and applicable HHS regulations, Defendants are required by the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) to obtain and produce data related to federally-funded published research findings that are used in developing agency actions having the force and effect of law.

40. Plaintiff's November 7, 2011 request satisfies the requirements of the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) because Requested Records are research data relating to published research findings produced under a federal award, and because such research data and published research findings have been used by the Federal Government in developing agency actions that have the force and effect of law.

41. Defendants have violated the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) by not obtaining Requested Records from the Grantee, and by not providing all Requested Records to Plaintiff.

42. Plaintiff has exhausted all available administrative remedies.

43. Plaintiff has been injured by being denied access to all Requested Records to which it is entitled and, as a result, being denied the ability to review all Requested Records.

COUNT II: VIOLATION OF THE APA
(5 U.S.C. §§ 702, 706)

44. The foregoing paragraphs are incorporated herein by reference.

45. On or about November 7, 2011, Plaintiff submitted to NIH a letter requesting the Requested Records, pursuant to and in compliance with the FOIA and applicable HHS regulations.

46. Upon information and belief, Defendants are in possession or control of, or have a right and obligation to obtain, all Requested Records.

47. Upon information and belief, the Grantee is in possession or control of Requested Records.

48. Defendants are required by the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) to obtain and produce data related to federally-funded published research findings that are used in developing agency actions having the force and effect of law, in response to a request submitted in conformance with the procedures established under the FOIA and applicable HHS regulations.

49. Plaintiff's November 7, 2011 request satisfies the requirements of the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) because Requested Records are research data relating to published research findings produced under a federal award, and because such research data and published research findings have been used by the Federal Government in developing agency actions that have the force and effect of law.

50. Defendants' refusal to obtain Requested Records from the Grantee, and Defendants' refusal to provide all Requested Records to Plaintiff, is arbitrary and capricious and contrary to law, including the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d), 45 C.F.R. § 74.36(d), and the APA.

51. Plaintiff has exhausted all available administrative remedies.

52. Plaintiff has no adequate remedy at law, as HHS has not timely responded to Plaintiff's appeal.

53. Plaintiff has been injured by being denied access to all Requested Records to which it is entitled and, as a result, by being denied the ability to review all Requested Records.

COUNT III: MANDAMUS
(28 U.S.C. § 1361)

54. The foregoing paragraphs are incorporated herein by reference.

55. On or about November 7, 2011, Plaintiff submitted to NIH a letter requesting the Requested Records, pursuant to and in compliance with the FOIA and applicable HHS regulations.

56. Upon information and belief, Defendants are in possession or control of, or have a right and obligation to obtain, all Requested Records.

57. Upon information and belief, the Grantee is in possession or control of Requested Records.

58. Defendants are required by the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) to obtain and produce data related to federally-funded published research findings that are used in developing agency actions having the force and effect of law, in response to a request submitted in conformance with the procedures established under the FOIA and applicable HHS regulations.

59. HHS regulations impose upon Defendants a mandatory, non-discretionary duty to obtain Requested Records from the Grantee and to provide such Requested Records to Plaintiff.

60. Defendants have not obtained Requested Records from the Grantee so that they can be made available to Plaintiff.

61. Defendants have violated the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) by refusing to obtain Requested Records from the Grantee, and by refusing to provide all Requested Records to Plaintiff.

62. Plaintiff has exhausted all available administrative remedies.

63. Plaintiff has no adequate remedy at law, as HHS has not timely responded to Plaintiff's appeal.

64. Plaintiff has been injured by being denied access to all Requested Records to which it is entitled and, as a result, being denied the ability to review all Requested Records.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff hereby requests:

a. An order declaring that Plaintiff is entitled to all Requested Records;

b. An order requiring Defendants to obtain Requested Records from the Grantee, and to provide all Requested Records to Plaintiff;

c. A writ of mandamus compelling Defendants to obtain Requested Records from the Grantee, and to provide all Requested Records to Plaintiff;

d. An order declaring Defendants' actions to be in violation of the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d), 45 C.F.R. § 74.36(d), and the APA;

e. Reasonable attorneys' fees;

f. Costs of suit; and

g. Such other relief as this Court deems just and proper.

Dated: July 12, 2012

ARNOLD & PORTER LLP

By: _____

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